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Fairview Pharmacy Services clozapine monitoring program: Description and evaluation of a clinical pharmacy service

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Abstract

Fairview Pharmacy Services, part of an academic health system, comprises 35+ outpatient pharmacies in Minneapolis, Minnesota. In 2013, the nonprofit organization opened a satellite location at the University of Minnesota Psychiatry Clinic. The original goals of the service were to improve patient satisfaction and medication adherence through comprehensive pharmaceutical care and clinic provider support. A clozapine monitoring program was envisioned and developed by the pharmacists and now provides optimal medication monitoring, dispensing, and coordination for approximately 100 patients.

Keywords: clozapine monitoring, Fairview Pharmacy Services, medication management

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Introduction

Clozapine is an atypical antipsychotic indicated for treatment-resistant schizophrenia.[1] A risk evaluation and mitigation strategy (REMS) program was initiated for absolute neutrophil count (ANC) monitoring in an effort to prevent medication-associated severe neutropenia. The administrative responsibilities, coordination complexities of medication dispensing and lab monitoring, and communication among patient, prescriber, pharmacy, and lab may result in underuse of the medication.[2] Fairview Pharmacy Services (FPS) sought to address this lack of coordinated care and developed a clozapine monitoring program with the University of Minnesota Psychiatry Clinic (UMPC) to streamline medication access and neutropenia monitoring.

Background

Fairview Health Services, in partnership with the University of Minnesota (UMN), is a network of hospitals, primary care and specialty clinics, and retail pharmacies, and is one of the largest health care providers in Minnesota. Fairview's Medication Therapy Management program has been providing comprehensive medication management (CMM) for almost 20 years. Currently, the program includes 31 Medication Therapy Management pharmacists working in 44 locations, including primary care and specialty clinics.

The UMPC sees an average of 100 patients daily, about 10% of whom are new to the clinic each month. Clinical care is provided by about 20 psychiatry residents and fellows, 5 midlevel practitioners, and 15 faculty psychiatrists, in addition to 18 psychologists, 3 social workers, and 5 nurses.

In 2013, FPS established a pharmacy satellite within the UMPC with the initial goals of (1) improving patient medication adherence, (2) increasing prescription capture rate, (3) providing CMM to patients, and (4) providing pharmaceutical support to the clinic providers. The need for a streamlined clozapine monitoring process was quickly identified, and infrastructure was developed to support a monitoring program. The clozapine monitoring program (CMP) has expanded to nearly 100 patients from multiple health systems during the last 5 years.

Clozapine is an atypical antipsychotic indicated for (1) the treatment of severely ill patients with schizophrenia who fail to respond adequately to standard antipsychotic treatment and (2) reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorder.[1]

The primary safety concern with clozapine is the risk of severe neutropenia (ANC <500/μL), which, although rare, can lead to serious infections and death. Neutropenia (ANC <1500/μL) is estimated to occur in about 4% of patients receiving clozapine.[3] Because of the risk of this serious adverse event, a REMS program was mandated for clozapine patients and prescribers. The program requires initial and ongoing lab draws to monitor for neutropenia prior to patients receiving clozapine from the pharmacy; however, coordination of this requirement can be cumbersome for all parties and can become a barrier to medication access.[2]

Prior to the Fairview CMP, lab orders and clozapine prescriptions were sent to an off-site pharmacy for processing. Mobile phlebotomists delivered medication at blood draw appointments, and lab results were faxed to the clinic within a few days. Because of a lack of clinic electronic medical record (EMR) access, communication delays or errors were frequent, and information about missed blood draws was inconsistently shared. The development of a clozapine monitoring program by FPS that allowed both prescribers and pharmacists immediate access to lab results became a clear solution.

Fairview's pharmacists first provided CMP to UMPC patients upon prescriber referral and coordinated blood draws at a Fairview clinic or at the UMN campus in conjunction with psychiatry clinic appointments. The need for mobile phlebotomy was quickly apparent in order to increase program access, streamline the monitoring process, and increase marketability of the pharmacy to this patient population.

Pharmacists coordinated with FPS and Fairview phlebotomy teams to hire a mobile phlebotomist for these patients, and the home draw option was made available in September 2014.

Service Description/Methods

The CMP is operated by 2 clinical pharmacists who provide CMM for clinic patients, with 1 dedicated mental health pharmacy technician who coordinates clozapine dispensing/mailing and helps provide a patient reminder call after missed blood draws.

Patients are referred to CMP by the UMPC prescribers, UMN inpatient behavioral health units upon discharge, and other psychiatry prescribers who are familiar with the program. Any patient taking clozapine is eligible for the program, provided the patient receives medication through FPS. Upon referral, pharmacists:

1. Complete a CMM visit for clozapine education and to discuss ANC monitoring options (home or clinic draw with refill pickup or mail out). Follow-up CMM care is ongoing, as appropriate, dependent upon insurance coverage. Coordination with clinic prescriber is essential for side effect management, as collaborative practice agreement for such medications is not currently in place.
2. Enroll patient into clozapine REMS program via phone call (only prescriber designees are permitted to enroll patients online, and getting all retail pharmacy staff enrolled as such has been a challenge).
3. Enter lab results into REMS and dispense clozapine according to REMS guidelines.
4. Document current dose, monitoring frequency, lab result assessment, and next draw/refill date in the EMR. Notes are routed to the provider in the event of an abnormal result or late blood draw.
5. Alert phlebotomy scheduler of new patients or changes. Phlebotomy team calls a day prior to the scheduled home draw to confirm draw time.
6. Track when clozapine patients are due for blood draws to ensure they are completed in a timely manner and patient does not run out of medication. Pharmacists currently use patient lists in EMR and clinic calendars for coordination.
7. Refill clozapine and any other maintenance medications on behalf of the patient when they are due. Patients do not have to call in refills.
8. Help coordinate mailing medications. Package is double checked to ensure medication is mailed to the correct address.
9. Authorize new lab order for complete blood count with differential, per specific collaborative practice agreement for ANC monitoring, when order has expired.
10. Call patients with lab draw reminder if they have not rescheduled a missed draw.

Comprehensive medication management visits are billed to patient's medical insurance, but if the plan does not cover CMM, a subset of patients are able to continue receiving services if the patient receives other primary or specialty care within the health system. Medication is billed to the patient's pharmacy insurance, per usual practice. Home phlebotomy visits are currently billed to the pharmacy, but efforts are in place to be able to bill the patient's medical insurance. There is no billing structure in place for the care coordination and administrative

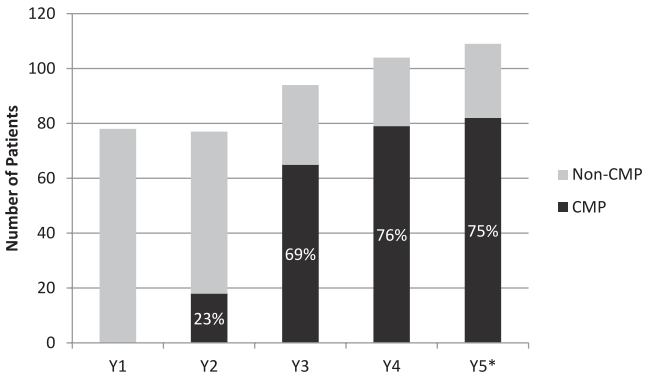

FIGURE: Clozapine patient and clozapine monitoring program (CMP) capture rate (Y5* indicates that a full year of data was not available at that time and includes September 2016-June 2017)

responsibilities of ANC monitoring and documentation by the CMM pharmacist.

Fairview Pharmacy Services sought to determine how the implementation of the CMP and home phlebotomy services impacted the total number of patients referred from the UMPC for clozapine monitoring. Data from the EMR and pharmacy dispensing records were evaluated to determine the total number of patients prescribed clozapine from the UMPC and proportion of those patients who had prescriptions filled through the Fairview CMP.

Results/Discussion

The CMP provides immediate access to lab results, thereby enhancing the continuity of care between clinic, pharmacy, and patient. Although no provider satisfaction survey has been formally distributed, prescribers have reported feeling more confident that labs are being appropriately monitored and that their patients are getting the medication in a timely manner.

The number of UMPC patients prescribed clozapine increased from 78 to 110 during the 5-year time span. Among patients seen at this clinic, the proportion enrolled in the CMP increased substantially since the program's initiation (Figure). Furthermore, the addition of mobile phlebotomy services at the start of year 3 is likely to have contributed to the increase from 23% to 69% of patients in the CMP. As of June 2017, the average duration of clozapine therapy for CMP patients was 598.7 days compared with 267.4 days for patients who were dispensed clozapine through a Fairview Pharmacy but not part of the CMP ($P < .001$). The longest duration of therapy in the CMP group was 1250 days, which supports the hypothesis that many patients who are part of the program are able to sustain treatment for several years.

Conclusion

The implementation of a CMP increased confidence in clozapine prescribing, as evidenced by the increased number of patients prescribed the medication. The program was also attractive to prescribers to allow more seamless patient care, and the data suggest that patients in the program are significantly more adherent to their medication. Future research in comparing CMP to other programs would be valuable, in addition to developing a report to better track medication adherence. A cost analysis would also be useful to determine how pharmacist time can be best used. Furthermore, a formal evaluation of the prescriber experience would be interesting and could help guide further program development.

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